Rightest™ *GS300* BLOOD GLUCOSE TEST STRIP INSERT

Intended Use

The ***Rightest***™ Blood Glucose Monitoring System is used by individuals with diabetes.

It is for the checking on glucose levels in capillary whole blood (CB) from the finger, as an aid in management of diabetes at home and clinical sites.

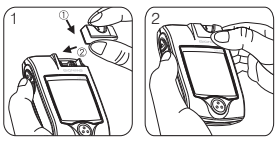
Rightest™ test Strips are intended for testing outside the body (*in vitro* diagnostic use) (For self-testing) only.

The ***Rightest***™ System tests the CB and provides results equivalent to a laboratory instrument.

- The ***Rightest***™ Blood Glucose Test Strip is designed for use with the ***Rightest***™ Blood Glucose GM300/GM110 Meter.
- The ***Rightest***™ Blood Glucose Monitoring System includes meter, Test Strips, Smart Code Key, Check Key, control solutions, lancing device and lancets.

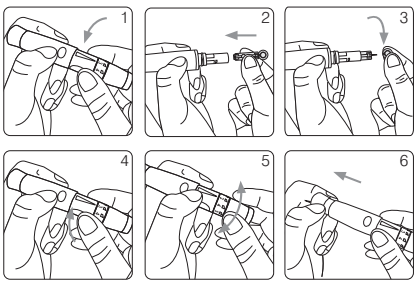
Test Procedure

REFER TO THE ***Rightest***™ USER'S MANUAL FOR MORE DETAILED INFORMATION.



Smart Code Key Installation (only for GM300 Meter)

1) With the Meter off, follow ① and ② direction to put the new Smart Code Key into the track on code key base.
2) Push down the Smart Code Key until it snaps into the Smart Code Key base.

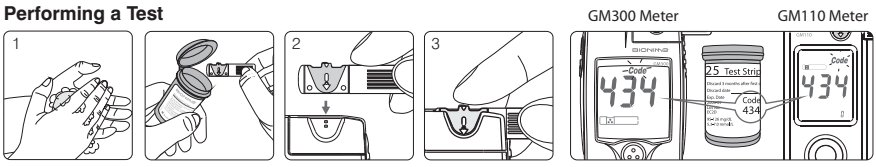


Preparing the Lancing Device
(Please see detailed information in User Manual)

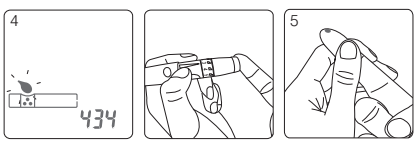
1) Unscrew the head of lancing device.
2) Load a lancet into the lancing device.
3) Twist off the protective cover of lancet and keep it (You will need it after testing).
4) Screw back the head of lancing device.
5) Twist the comfort dial of lancing device to select the lancet depth. Start at 2 or 3.
   For tougher skin, dial to a higher number.
6) Pull the plunger of lancing device until the end and release your hand. Your lancing device is ready. Then set it aside; you will need it in the next step.

NOTE
Different meter kit might be with different lancing device, please follow the instructions in respective User Manual to make sure you perform the test correctly.

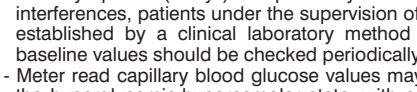
Performing a Test



1) Wash and dry your hands. Take one strip from the vial. Close the vial cap immediately.
2) Insert the strip into the strip port on meter with the indication symbol facing up. Push the strip in until it snaps and stops. The meter will turn on automatically.
3) Make sure the code number on the meter screen matches the code number on the test strip vial.
4) When you see the flashing blood drop, hold the lancet device to side of your fingertip and press the release button.
5) Gently squeeze your fingertip to get a drop of blood. Our meter only needs a tiny blood sample.



Sample Size Example



We suggest you to take 1.4~2.5μl to do the test on glucose monitoring system. Blood sample size above 4.0μl is too much which might contaminate the Smart Code Key.

6) Touch and hold the drop to the edge of sample entry until you hear a " beep " and the view window is totally filled with blood. If the view window is not totally filled with blood or the test does not start. Then discard the test strip and repeat the test with a new test strip.
7) You will see the countdown mode on the screen. After 8 seconds, the test result appears. For more information about your test results, please see your User Manual.
8) To remove the lancet, unscrew the head of lancing device and put the protective cover of lancet on the table. Stick the lancet into the Protective cover by holding the lancing device it into a puncture-proof container.

For more information on how to use your meter and understand your test results, see the User Manual.

Test Result

- Blood glucose test results are shown on the meter as mg/dL or mmol/L, depending on which unit of measurement you have chosen. Consult your doctor before making any changes to your diabetes medication program.
- If your blood glucose result is unusually high or low, or if you question your results, repeat the test with a new test strip. You can also run a quality control test with your ***Rightest***™ Check Key and ***Rightest***™ Control Solutions to check your meter and strip. If the test result still remains unusually high or low, contact your doctor immediately.
- If you are experiencing symptoms that are not consistent with your blood glucose test results and you have followed all the instructions in this manual, contact your doctor immediately.
- The ***Rightest***™ Meter displays results between 10 and 600 mg/dL or 0.6 and 33.3 mmol/L. If your test result is below 10 mg/dL (0.6 mmol/L), " Lo " will appear on the screen. Please repeat your test again with another strip. If you still get a " Lo " result, you should immediately contact your doctor.
- If your test result is above 600 mg/dL (33.3 mmol/L), " Hi " will appear on the screen. Please repeat your test again with another strip. If you still get a " Hi " result, you should immediately contact your doctor.

Expected values

Time	Range (mg/dL)	Range (mmol/L)
Fast for 8 hours:		
Pre-diabetes	100 – 125	5.6 – 6.9
Diabetes	>126	>7.0
After eating or oral glucose tolerance test (in the 2 hours):		
Pre-diabetes	140 – 199	7.8 – 11.1
Diabetes	>200	>11.1

Precautions

- Check the expiration date printed on the package every time you use the strip. Do not use expired test strips.
- Close the vial cap immediately after taking test strip out from the vial.
- Do not perform quality control test with expired control solution.
- Do not bend or twist the test strip. Damage of test strip may cause wrong result.
- Do not reuse test strips.
- Do not reuse lancets. Discard used lancets properly.
- Wait at least 30 minutes to perform a test if you have moved the meter to an area of different temperature.
- If you want to purchase a new control solution, please contact your authorized Bionime representative.

Warning

- Keep the test strips or vial cap away from children. They may cause a choking hazard. If a test strip or vial cap is swallowed, contact your physician immediately.

Limitations

- Grossly lipemic (fatty) samples may interfere with some methodologies. To be aware of such interferences, patients under the supervision of their physician should have baseline glucose values established by a clinical laboratory method prior to starting home glucose monitoring. These baseline values should be checked periodically thereafter.
- Meter read capillary blood glucose values may be significantly lower than " true glucose levels " in the hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested by the ***Rightest***™ System, or tested with extreme caution.
- Caution is advised in the interpretation of glucose values below 50 mg/dL or above 250 mg/dL. Consult a physician as soon as possible if values in this range are obtained.

- Healthcare professionals should evaluate their technique and their patients' technique at periodic intervals. To accomplish this, it is recommended that BGM results be compared with a concurrently obtained laboratory measurement on the same blood sample. A well characterized clinical laboratory method employing hexokinase or glucose oxidase should be used as the comparative method.
- Fluoride should not be used as a preservation for venous specimens when using blood glucose monitors.
- Hands and fingers contaminated with sugar from foods or beverages may cause falsely elevated results.
- Differences in whole blood and serum/plasma values may cause variability in results.
- Storage of strips near bleach as well as bleach containing products will affect results of glucose oxidase strips.
- The use of cellular phones and other radio transmitting devices should be prohibited in areas where testing occurs.
- ***Rightest***™ Blood Glucose Test Strips are designed for use with capillary whole blood samples. Do not use serum or plasma samples.
- Incorrect test results may be obtained at high altitude more than about 10000 feet (3048 meters) above sea level.
- Hematocrits below 30% may cause higher results, and hematocrits above 55% may cause lower results.
- Severe dehydration and excessive water loss may cause inaccurately low results.
- ***Rightest***™ Blood Glucose Monitoring System has not been validated for use on neonates. Therefore, it should not be used for neonates.
- Do not perform the blood glucose test at temperatures below 10℃ (50℉) or above 40℃ (104℉), below 10% or above 90% relative humidity.

Storage and Handling
- Store the strips in the original capped vial at temperatures between 4℃ to 30℃ (39 to 86℉) and relative humidity below 90%. Do not freeze.
- Replace the vial cap immediately and close tightly after taking test strip out from the vial. Do not leave the cap of vial opened. If the strip is exposed in the air too long, it will absorb the moisture and cause wrong test result.
- Use test strips within 3 months after first opening.

Measurement Range
The measurement range of the ***Rightest***™ System is 10 to 600 mg/dL or 0.6 to 33.3 mmol/L.

Quality Control Section
Please refer to the Quality Control section of the User Manual.

Accuracy
The accuracy of the test study of the ***Rightest***™ Blood Glucose Meter was demonstrated by comparing whole blood (plasma equivalent) glucose values on the ***Rightest***™ meter with plasma glucose values on a lab instrument.
A total of 176 patients were enrolled. Each patient collected and tested their own blood samples (from the fingertip) using the ***Rightest***™ Meter. Another blood sample was collected within 5 minutes and got the plasma to be analyzed on the lab instrument. Ninety-seven percent of the results were within +/- 20% of the comparison method results at glucose concentrations ≧75 mg/dL and within +/-15 mg/dL at glucose concentrations <75 mg/dL.

Troubleshooting and Customer Service
For more information on error messages and trouble shooting, please refer to the Error Messages and Trouble Shooting section of the ***Rightest***™ User manual.
You may also contact customer service by calling 886 4 24951268 (08:30 - 17:30, GMT + 08:00).
(At all other times, you could contact your healthcare professional for assistance)

Additional Information for Healthcare Professionals

Detection Principle
The glucose oxidase and potassium ferrocyanide in the strip react with the glucose in the sample to produce an electrical current which is proportional to the amount of glucose in the sample. The meter measures the current and converts it to the corresponding glucose concentration.

Performance Characteristics
Measurement Range
The measurement range of the ***Rightest***™ System is 10 to 600 mg/dL or 0.6 to 33.3 mmol/L.

Precision
The precision was evaluated including (i) venous whole blood sample (ii) 3 levels glucose control solution in period of 20 days, by 10 meters and 1 batch of strip.

(i) Venous whole blood sample:

Meters	P-01	P-02	P-03	P-04	P-05
(1) Total test numbers (n)	100	100	100	100	100
(2) Mean mg/dL (mmol/ L)	40.6(2.3)	96.9(5.4)	117.3(6.5)	192.9(10.7)	351.5(19.5)
(3) SD mg/dL (mmol/ L)	1.5(0.08)	2.5(0.14)	2.5(0.14)	3.9(0.22)	6.3(0.35)
(4) CV (%)	3.6%	2.6%	2.1%	2.0%	1.8%

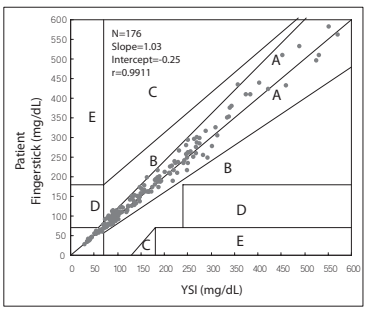
(ii) Control solution:

Glucose levels	CS-L	CS-N	CS-H
(1) Total test numbers (n)	100	100	100
(2) Mean mg/dL (mmol/ L)	50.5(2.3)	102.2(5.8)	302.3(16.7)
(3) SD mg/dL (mmol/ L)	1.2(0.06)	2.0(0.11)	6.6(0.36)
(4) CV (%)	2.5%	1.9%	2.2%

Accuracy
The accuracy of the test study of the ***Rightest***™ Blood Glucose Meter was demonstrated by comparing whole blood (plasma equivalent) glucose values on the ***Rightest***™ meter with plasma glucose values on a lab instrument.
A total of 176 patients were enrolled. Each patient collected and tested their own blood samples (from the fingertip) using the ***Rightest***™ Meter. Another blood sample was collected within 5 minutes and got the plasma to be analyzed on the lab instrument.
Linearity regression produced the following line equation (Lab instrument-YSI 2300D was considered to be the reference method):

Patient	*Rightest*™ fingertip vs YSI-Plasma
Test range	30~572 mg/dL (1.7~31.8 mmol/L)
Test number	176
Slope	1.03
Intercept (mg/dL)	-0.25
r	0.9911

Interferences
The following compounds may interfere with the glucose measurement at the concentrations listed:
Uric acid > 0.54 mmol/L (> 9.0 mg/dL)
L -Dopa > 0.076 mmol/L (> 1.5 mg/dL)
Methyldopa > 0.071 mmol/L (> 1.5 mg/dL)
Cholesterol > 6.5 mmol/L (> 250 mg/dL)



Reagents
Each Blood Glucose Test Strip contains the following reagents:

Glucose Oxidase (Aspergillus niger) (GOD)	8.5 %
Potassium ferricyanide	48.5 %
Non-reactive ingredients	43 %

References

1) Consensus statement on self monitoring of blood glucose. Diabetes Care 1987; 1:95-99.
2) Diabetes Information - American Diabetes Association and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

IVD	For in vitro diagnostic use		Manufacturer	LOT	Lot number
	Use by	4℃ 30℃	Store between temperature 4℃ and 30℃ (39℉ and 86 ℉)		

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